

## REMARKS

Applicants have developed a device for both collecting and drying a liquid biological sample at a first location, and then mailing the dried sample to a clinical laboratory remotely located from the first location for analysis. A preferred version of Applicants' device includes a strip having a handle end and a collection end. The collection end has attached thereon a collection pad. The device also includes a dried biological sample on the collection pad, as well as a means for facilitating removal of at least a portion of the collection pad from the strip to recover the analyte for detection or measurement by laboratory analysis.

Because the device is used with dry samples, among other things, it advantageously provides (a) increased sample stability especially to the higher temperatures encountered in mailing (b) lighter weight requiring less postage, (c) significantly reduced risk of accidental leakage during transport (a dried sample being less likely to leak than a liquid sample), and (d) rapid removal of the sample from the device to facilitate analysis at the clinical laboratory.

Another version of Applicants' device includes a strip having a handle end and a collection end. The collection end has attached thereon a collection pad for collecting and drying a liquid biological sample containing the analyte. The collection pad includes a sponge-like material comprising polyvinyl alcohol. The sponge-like material is advantageous in its ability, relative to other materials, to absorb and dry large quantities of a liquid sample. It is also advantageous in that it is substantially non-reactive and compatible with a blocking agent such as BSA. In comparison to other materials, these advantages allow the sponge-like material comprising polyvinyl alcohol to be used for the measurement of a very dilute analyte in a liquid biological sample (e.g., microalbumin in urine).

### Claim Status

Claims 1-12 and 19-26 were pending in the application. In the Office Action, the page entitled "Office Action Summary" indicates that claims 1-12 and 21-26 (not 19-26) were pending. Applicants believe this indication to be a mistake, but request clarification. In the body of the Office Action, claims 1-12 and 19-26 were rejected for the reasons described in more detail below.

In this amendment, no claims have been cancelled; claims 1-3, 19, and 24 have been revised; and new claims 27-42 have been added. Accordingly, claims 1-12 and 19-42 are currently before the Examiner for consideration.

### Rejections

In the Office Action, claims 1, 4, 7, 8, 10, 19, 21, 22 and 24-26 were rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 5,609,160 to Bahl et al (hereinafter referred to as "Bahl").

Claims 1 and 19 have herewith been amended to recite a dried biological sample contacting the collection pad. Bahl fails to disclose a dried biological sample contacting a collection pad. 35 U.S.C 102 requires that for a claim to be anticipated each and every element of that claim must be found in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Since Bahl does not disclose a dried biological sample on a collection member, neither claim 1, claim 19, nor any claim depending from claims 1 or 19 are anticipated by the reference. Accordingly, withdrawal of the rejection is requested.

### Rejections Under 35 USC 103

In the Office Action, claims 5, 11, 12, 20 and 23 were rejected under 35 U.S.C. 103(a) as being unpatentable over Bahl et al '160 and further in view of U.S. Patent 6,165,416 to Chandler (hereinafter referred to as "Chandler").

Regarding claim 20, neither Chandler nor Bahl disclose or suggest a urine collection cup for collecting a urine sample.

Regarding claims 11-12, the Office Action concludes that "...it would have been obvious to one of ordinary skill in the art to incorporate multiple apertures and collection pads so that multiple tests or assays may be performed in a single support." No support or reasoning is provided as to how the conclusion was reached in light of the cited references. Applicants refer the Examiner to the second full paragraph of page 12 of Applicants' amendment filed January 23, 2001, in which Applicants requested further explanation or withdrawal of the rejection. The Office Action did not respond to Applicants' request. Again, as Applicants do not understand the basis of this rejection, further explanation or withdrawal of the rejection is requested

As to rejections under 35 USC 103, MPEP 2143 sets out the three basic criteria required for making out a prima facie case of obviousness:

First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

As indicated above, claims 1 and 19 have herewith been amended to recite a dried

biological sample contacting the collection pad. Neither Bahl or Chandler teach or suggest a dried biological sample on a collection pad. Thus, as not all the present claim limitations are taught or suggested by the cited references, a prima facie of obviousness based on the cited references cannot be established for the inventions of claim 1, claim 19, or any claim depending from these claims. Accordingly, withdrawal of the rejection is requested.

In the Office Actions, claims 2, 3, 6, and 9 were rejected under 35 U.S.C. 103(a) as being unpatentable over Bahl et al '160, and further in view of U.S. Patent 5,656,503 to May et al (hereinafter May).

With regard to claim 3, Applicants note that May does not teach a collection pad having thereon albumin derived from urine.

With regard to claim 6, May does not teach an absorbent material "comprising" polyvinyl alcohol. Rather, May teaches a porous material "treated" with polyvinyl alcohol to block binding sites.

Claims 1 and 19 now recite a dried biological sample contacting the collection pad. Neither Bahl or May teach or suggest a dried biological sample on a collection pad. Thus, not all the present claim limitations are taught or suggested by the cited references. The inventions of claim 1, claim 19, and all claims depending from these claims are thus patentably distinct over the cited references. Accordingly, withdrawal of the rejection is respectfully requested.

#### New Claims 27-40

New claims 27-40 are believed patentable over the references cited in this application because independent claim 27 (from which claims 28-40 ultimately depend) recites a collection

pad that comprises a sponge-like material comprising polyvinyl alcohol. As indicated above, May teaches a porous material "treated" with polyvinyl alcohol to block binding sites, but does not teach an sponge-like material "comprising" polyvinyl alcohol.

### Conclusion

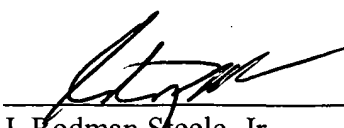
The currently pending claims are supported throughout the specification and are patentable over the prior art. No new matter has been added. Allowance of all pending claims is respectfully requested.

The fee for the added claims (16 additional and one independent claim) is enclosed. This amendment is accompanied by a Petition for a Retroactive Extension of Time for one month and the fee for such petition. The Commissioner is hereby authorized to charge any underpayment or credit any overpayment of fees under 37 CFR 1.16 or 1.17 as required by this paper to Deposit Account 50-0951.

The Examiner is invited to call the undersigned if clarification is needed on any matter within this Amendment, or if the Examiner believes a telephone interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,

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